

## 510(k) Summary of Safety and Effectiveness

JUL 10 2006

### Triage® TOX Drug Screen Controls

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: (To be determined) **k 060788**

#### A. Name and Address of Submitter

Company Name:	Biosite Incorporated
Address:	9975 Summers Ridge Road San Diego, CA 92121
Telephone:	(888) 246-7483
Fax:	(858) 586-7543
Contact Person:	Robin Weiner
Date Summary Prepared:	03/21/06

#### B. Device Names

1. Trade Name

Triage® TOX Drug Screen Controls

2. Common / Usual Name

TOX Drug Screen Controls

3. Classification Name

Drug Mixture Control Materials  
21 CFR 862.3280  
Class I

Product Code: DIF

#### C. Predicate Devices

Biosite Triage® TOX Drug Screen Controls (K050037)

#### D. Device Description and Intended Use

The Triage TOX Drug Screen Controls are to be used with the Triage TOX Drug Screen tests and Triage Meters to assist the laboratory in monitoring test performance.

#### E. Summary of Comparison Data

The table below provides a comparison of the technical principles between the Triage TOX Drug Screen Controls and the predicate device.

Characteristic	Triage TOX Drug Screen Controls (proposed)	Triage TOX Drug Screen Controls (K050037)
Intended Use	Assayed control for monitoring urine-based drugs of abuse assays	Assayed control for monitoring urine-based drugs of abuse assays
Matrix	Human Urine	Human Urine
Form	Liquid	Liquid
Analytes	Commonly abused drugs	Commonly abused drugs
Storage	-20 °C or colder	-20 °C or colder

#### F. Conclusion

The information provided in the premarket notification demonstrates that the Triage TOX Drug Screen Controls are substantially equivalent to previously approved predicate devices. The information provided assures that the Triage TOX Drug Screen Controls are safe and effective for their intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUL 10 2006

Ms. Robin Weiner  
Vice President  
Regulatory and Government Affairs  
Biosite Incorporated  
9975 Summers Ridge Road  
San Diego, CA 92121

Re: k060788  
Trade/Device Name: Triage® TOX Drug Screen Controls  
Regulation Number: 21 CFR§862.3280  
Regulation Name: Clinical toxicology control material  
Regulatory Class: Class I  
Product Code: DIF  
Dated: June 23, 2006  
Received: June 26, 2006

Dear Ms. Weiner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

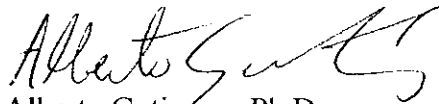
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Alberto Gutierrez", with a stylized flourish at the end.

Alberto Gutierrez, Ph.D.

Director

Division of Chemistry and Toxicology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K060788

Device Name: Triage® TOX Drug Screen Controls

Indications For Use:

The Triage TOX Drug Screen Controls are to be used with the Triage TOX Screen tests and Triage Meters to assist the laboratory in monitoring test performance.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson  
Division Sign-Off

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**Office of In Vitro Diagnostic Device  
Evaluation and Safety**

K060788